

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

552,011
PCT/IB2003/001295



Applicant's or agent's file reference DISNALET001	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB2003/001295	International filing date (day/month/year) 09 April 2003 (09.04.2003)	Priority date (day/month/year)
International Patent Classification (IPC) or national classification and IPC A61K 38/48, 35/78, 7/48, A61P 17/02		
Applicant GOMEZ TORRES, Harold, Armando		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 09 November 2003 (09.11.2003)	Date of completion of this report 18 July 2005 (18.07.2005)
Name and mailing address of the IPEA/RU	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IB2003/001295

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-22, 24-34, as originally filed
 pages _____, filed with the demand
 pages 23, filed with the letter of 09 November 2004 (09.11.2004)
- ☒ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages 35-3-, filed with the letter of 09 November 2004 (09.11.2004)
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language _____ which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims	1-11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

2. Citations and explanations

The examination statement is made on the basis of claims 1 to 11, as amended on 09 November 2004, in the light of the documents cited in the search report:

D1: US 5 024 838 A (1991-06-18)

D2: WO 00/37037 A (2000-06-29)

D3: WO 93/20838 A (1993-10-28)

D4: WO 98/53850 A (1998-12-03)

Document D1 relates to a topical composition in the form of a gel for treating skin, including an antiseptic, sapogenin, a proteolytic enzyme (papain) and a thickening agent (carboxymethylcellulose).

D2 relates to a topical composition in the form of a gel for treating skin burns, including one or more organic acids (acetic acid, citric acid), a plant-based agent, a protective agent (carbopol) and an anaesthetic agent.

D3 relates to a topical composition for treating skin burns and wounds, in the form of a hydrophilic gel or in the form of a gel in combination with a water-soluble polymer, and including a proteolytic enzyme (papain).

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D4 relates to a topical composition for treating skin, including a proteolytic enzyme (papain).

An analysis of the prior art (D1 to D4) shows that it does not include an indication of the composite composition as per amended claim 1. Furthermore, none of the cited documents includes information on the presence of an emulsifier (triethanolamine) and a preservative (methyl paraben and propyl paraben) in therapeutic compositions.

Given that the composition according to claim 1 is not known or obvious and has an effective pain-killing activity as well as protective, wound-healing and anti-inflammatory activities, claims 1 to 9 comply with the requirements of novelty and inventive step. Claims 10 and 11 also comply with the requirements of novelty and inventive step because they refer to claims 1 to 9.

Claims 1 to 11 comply with the requirement of industrial applicability.